

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER 4705-0121PUS1 U.S. APPLICATION NO. <b>10/582385</b> (known to see 37 CFR 1.5)
INTERNATIONAL APPLICATION NO. PCT/BR2004/000242	INTERNATIONAL FILING DATE 10 December 2004	PRIORITY DATE CLAIMED 12 December 2003
TITLE OF INVENTION PROCESS FOR THE PREPARATION OF ANHYDROUS AND HYDRATED ACTIVE PHARMACEUTICAL INGREDIENTS (APIS); STABLE PHARMACEUTICAL COMPOSITIONS PREPARED FROM THE, etc.		
APPLICANT(S) FOR DO/EO/US Marco Antônio SANTINI; Antônio MACHADO; Aurélio MARANDUBA; Eneida GUIMARÃES; Marcio SANTIAGO JUNIOR; Maria SILVA; Richard GRAZUL		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input checked="" type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
<b>Items 11 to 20 below concern document(s) or information included:</b>		
11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. 14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (If known, see 37 CFR 1.53) <b>10/582385</b>	INTERNATIONAL APPLICATION NO. PCT/BR2004/000242	ATTORNEY'S DOCKET NUMBER 4705-0121PUS1	
20. <input checked="" type="checkbox"/> Other items or information: Return Receipt Postcard PCT/ISA/210 Drawings - One (1) sheet			
The following fees have been submitted		<b>CALCULATIONS</b>	<b>PTO USE ONLY</b>
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300		\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 All other situations ..... \$200		\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400 All other situations ..... \$500		\$ 400.00	
<b>TOTAL OF 21, 22 and 23 =</b>		\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.			
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE
62 - 100 =	/50 =		x \$250.00
			\$
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	49 - 20 =	29	x 50.00
Independent claims	7 - 3 =	4	x 200.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+	360.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>		\$ 3,640.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.			
<b>SUBTOTAL =</b>		\$ 3,640.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$	
<b>TOTAL NATIONAL FEE =</b>		\$ 3,640.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		\$	
		\$	
<b>TOTAL FEES ENCLOSED =</b>		\$ 3,640.00	
		Amount to be refunded:	\$
		Amount to be charged	\$

IAP18 Rec'd PCT/PTO 09 JUN 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- 10/582385
- a. ☒ A check in the amount of \$ 3,640.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. 02-2448 in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

  
SIGNATURE

June 9, 2006

Mark J. Nuell, Ph.D.  
NAME

CUSTOMER NUMBER: 02292

36,623  
REGISTRATION NUMBER

/dns

10/582385  
AP18 Rec'd PCT/PTO 08 JUN 2006

Docket No.: 4705-0121PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
Marco Antônio SANTINI et al.

Application No.: NEW

Confirmation No.: N/A

Filed: June 9, 2006

Art Unit: N/A

For: PROCESS FOR THE PREPARATION OF  
ANHYDROUS AND HYDRATED ACTIVE  
PHARMACEUTICAL INGREDIENTS (APIS);  
STABLE PHARMACEUTICAL  
COMPOSITIONS PREPARED FROM THE  
SAME AND USES OF SAID COMPOSITIONS

---

Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The PTO is requested to use the amended sheets/claims attached hereto (which correspond to Article 19 amendments or to claims attached to the International Preliminary Examination Report (Article 34)) during prosecution of the above-identified national phase PCT application.

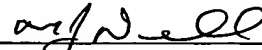
If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Application No.: NEW

Docket No.: 4705-0121PUS1

Dated: June 9, 2006

Respectfully submitted,

By 

Mark J. Nuell, Ph.D.

Registration No.: 36,623

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachment(s)